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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,054	01/07/2002	Andrew Darrow	ORT-1560	3780

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EXAMINER

MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/041,054

Applicant(s)

DARROW ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-8,14,21 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-8,14,21 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Applicant's Amendment filed December 15, 2003, has been entered. Amendments to claims 1, 2, 4, 14, and 21 introducing the transitional phrase, "corresponding to", also occurring in the new claim 28, and amendments to claims 5 and 8 introducing the transitional phrase "corresponds to", also occurring in the new claims 29 and 30, require restatement of the rejections of record under 35 U.S.C. § 112, first paragraph, for lack of adequate written description and lack of enablement, and require a new rejection under 35 U.S.C. § 112, second paragraph, of claims herein for indefinite description, as well as require restatement of the rejections of record over the prior art.

*Claim Rejections - 35 USC §112***The following is a quotation of the first paragraph of 35 U.S.C. § 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 5, 7, 8, 14, 21, and 28-30 are rejected, essentially for reasons of record, under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed December 12, 2003, have been fully considered but they are not persuasive. Applicant suggests that the claim amendments recite subject matter adequately described by the specification but ambiguous terms - "corresponding to" and "corresponds to" - introduced into the claims 1, 2, 4, 5, 8, 14, 21, and 28-30, and affecting claim 7 which depends from claim 4, vitiate the argument. Claim 21 is now included in this rejection because the amendatory transitional phrase "corresponding to" permits a claimed kit to comprise protease-encoding nucleic acid sequences not disclosed by the specification. The new, amendatory, phrases "corresponding to" and

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"corresponds to" are nowhere defined in the specification and are construed according to statements at lines 26-29 at page 2 of the specification to express a scope including "homologues", "genomic equivalents" and "mutant forms" of SEQ IDs NOs:1 and 8 that need encode neither the native protease T amino acid having the amino acid sequence set forth in SEQ ID NO:7 nor the zymogen fusion having the amino acid sequence set forth in SEQ ID NO:9. Proteases encoded by the "homologues", "genomic equivalents" and "mutant forms" would indeed "correspond to" the native protease T amino acid sequence set forth in SEQ ID NO:7 but the specification fails to provide an adequate written description of a nucleic acid that encodes any of the undisclosed, "corresponding" proteases or the "corresponding" nucleic acid sequences encoding them.

There is no evidence in the specification that Applicant possessed "corresponding" "homologues", "genomic equivalents" or "mutant forms" of a nucleic acid sequence that encodes the catalytic domain of the human serine protease T present within the amino acid sequence SEQ ID NO:7 at the time the parent application was filed. The protease having the amino acid sequence set forth in SEQ ID NO:9 is an artificial product that comprises the amino acid sequence of the native protease T catalytic domain and it is agreed that Applicant need not disclose alternative fusion proteins that comprise the native serine protease T catalytic domain to demonstrate inherent possession of generic fusion proteins comprising the native serine protease T catalytic domain. Yet nothing in the specification shows that Applicant had determined, or even contemplated, those positions among the carboxyl-proximal 260 amino acids of the T protease that might be altered, nor the nature of any amino acid substitution, nor any deletion of amino acids to generate a fragment. The rejection of record is sustained because the specification provides no written description that demonstrates Applicant's possession of any of the "corresponding" subject matter described by the amended claims or new claims.

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Claims 1, 2, 4, 5, 7, 8, 14, 21, and 28-30 are rejected, essentially for reasons of record, under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for nucleic acid molecules encoding a serine protease T having the catalytic domain amino acid sequence set forth in SEQ ID NO:7, and vectors, transformed host cells, kits, and methods of recombinant production of a serine protease T comprising, or utilizing, said nucleic acid molecules,

does not reasonably provide enablement for nucleic molecules encoding any and all amino acid sequences "corresponding to" the amino acid sequence of the serine protease T having the catalytic domain amino acid sequence set forth in SEQ ID NO:7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed December 12, 2003, have been fully considered but they are not persuasive. Applicant suggests that the claim amendments recite subject matter enabled by the specification but the ambiguous terms, "corresponding to" and "corresponds to", that the amendments introduce in claims 1, 2, 4, 5, 8, 14, 21, and 28-30, affecting claim 7 which depends from claim 4, vitiate the argument. Claim 21 is now subject to this rejection because it now recites "an amino acid sequence corresponding to SEQ ID NO:7". It is agreed that isocoding DNAs encoding the catalytic domain present both in the native protease T having the amino acid sequence set forth in SEQ ID NO:7 and in the zymogen-protease T fusion protein having the amino acid sequence set forth in SEQ NO:9 are enabled by the state of the art taken together with the specification, but claims 1, 2, 4, 5, 7, 8, 14, 21, and 28-30 now embrace "homologues", "genomic equivalents" and "mutant forms" of SEQ IDs NOs:1 and 8 that need encode neither the native protease T amino acid having the amino acid sequence set forth in SEQ ID NO:7 nor the zymogen fusion having the amino acid sequence set forth in SEQ ID NO:9. The specification does not enable the preparation of nucleic acid sequences encoding "homologues", "genomic equivalents" and "mutant forms" of the native human protease T sustaining arbitrary assignments of any or all codon deletions, additions, or substitutions that later the amino acid sequence of the human protease T catalytic domain of SEQ ID NO:7. The rejection of record is sustained because the specification

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does not teach one of skill in the art where, or how, nucleic acid sequences encoding the T protease catalytic domain within SEQ ID NO:7 might be altered by introducing any number of alternative codons and still permit expression of a functioning catalytic domain comprising unspecified amino acid insertions, deletions, or substitutions anywhere, in any combination or pattern.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 5, 7, 8, 14, 21, and 28-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 4, 5, 8, 14, 21, and 28-30 are indefinite in reciting “corresponding to” and “corresponds to” because the artisan and the public seeking to construe the scope of the amended claims can know neither the degree nor nature of the “correspondence” that Applicant intends. Is correspondence merely isologous coding capacity in a nucleic acid sequence - specifying disclosed amino acid sequences set forth in SEQ IDs NOs:7 and 9 - or does correspondence permit variation in a disclosed amino acid sequence? Claim 7 is subject to this rejection because it incorporates the indefinite limitation of the claim from which it depends without resolving the ambiguity. Claim 21 is independently rejected as indefinite because the amendment of December 15, 2003, states a grammatically ambiguous sentence. Even if Applicant had intended to set forth a Markush group, which might properly be stated “selected from the group consisting of SEQ ID NO:1, SEQ ID NO:7, and a nucleic acid”, this would be improper because there are only two structurally defined species presented the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 7, 8 and 28-30 are for reasons or record rejected under 35 U.S.C. § 102(b) as being anticipated by Antalis et al., WO 98/36054, of record.

Antalis et al. disclose, see Figure 20C, SEQ ID NO:30, pages 10, 18, and Example 15 at pages 52-53 and claims 19-21, 26, and 27, a nucleotide sequence encoding a serine protease designated SP003LA that clearly "corresponds to" the nucleic acid sequences of SEQ IDs NOs:1 and 8 herein where the amino acid sequence deduced sharing 100% sequence identity with the amino acid sequence of the native T protease from position 26 to position 290, inclusive. The rejection of record is sustained because the catalytic domain of the SP003LA product that Antalis et al. identify as a serine protease is entirely identical to the catalytic domain of the native protease T disclosed herein, lacking only a portion of the signal peptide region to share complete identity with the protease T amino acid sequence of SEQ ID NO:7 of the instant application and sharing the same activation site sequence, thus clearly a "corresponding" molecule. Antalis et al. also disclose expression vectors and host cells comprising a nucleotide sequence encoding a SP003LA serine protease in a context for expression by the host cell, which may be a prokaryotic or an eukaryotic host cell, at pages 38 and 39, anticipating the subject matters of vectors and host cells claimed herein because they need not disclose construction of a particular expression vector comprising a SP003LA-encoding nucleotide sequence, or transformation of a particular host cell with such an expression vector, to meet limitations of the claims as amended on December 15, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

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ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(e), (f) or (g) prior art under 35 U.S.C. §103(a).

Claims 14 and 21 are for reasons of record rejected under 35 U.S.C. § 103(a) as obvious over Antalis et al., WO 98/36054, as applied to claims 1, 2, 4, 5, 7, 8 and 28-30 above, in view of Burgess et al., U.S. Patent No. 6,165,771, of record.

The teachings of Antalis et al., discussed above, are taken as before. Antalis et al. do not disclose the expression of the SP003LA serine protease in recombinant host cells, or the preparation of a kit comprising a nucleic acid sequence encoding the SP003LA, which clearly "corresponds to" the nucleic acid sequence encoding the protease T of SEQ ID NO:7 herein. Thus their further teaching at page 53 is again cited: They teach that the SP003LA-encoding nucleic acid sequence is present in a human chromosomal cluster of serine protease genes comprising the human testisin gene which Antalis et al. teach contributes to spermatogenesis and is implicated in testicular cancer, further teaching that these serine proteases genes may be "essential" for the processes of "sperm maturation and development", where the "loss or mutation of these genes may lead to testicular germ cell tumours and to other testicular abnormalities, such as infertility." Burgess et al. are again cited for their teaching the recombinant expression of the medically significant human serine protease designated HE2NW40, cols. 5-9, in several prokaryotic and eukaryotic host cell transformed with an expression vector comprising a polynucleotide encoding the HE2NW40 product, or variants thereof such as fusion polypeptides made suitable for extracellular secretion by a selected host cell or made suitable for recovery by affinity chromatography from the host cell culture or from lysed host cells after expression, in order to prepare diagnostic

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antisera to detect the presence or absence of the expression of the native human serine protease HE2NW40 in cells of human tissues. Burgess et al. also teach, col. 8, the preparation of a diagnostic kit comprising a polynucleotide encoding the human serine protease HE2NW40, or a fragment thereof, useful in diagnosing a disease or susceptibility to a disease.

The rejection of record is sustained because it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the SP003LA-encoding nucleotide sequence of Antalis et al. for the HE2NW40-encoding nucleotide sequence in a vector and host cell of the recombinant expression system of Burgess et al. in order to practice a method for expression of the SP003LA serine protease in recombinant host cells according to claim 14 herein and would also have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the SP003LA-encoding nucleotide sequence of Antalis et al., or a fragment thereof, for the HE2NW40-encoding nucleotide sequence, or a fragment thereof, in a diagnostic kit of Burgess et al. to prepare kit of claim 21 herein. This is because such an artisan would have been motivated by teachings of both Antalis et al. and Burgess et al. that their nucleotide sequences encode proteases associated with human disease states, or with susceptibility to disease in humans, and teachings of Burgess et al. that recombinantly expressing a human serine protease encoded by a human serine protease-encoding polynucleotide is advantageous for recovery of the expressed protease and preparation of diagnostic antisera therewith, as well as teachings of Burgess et al. that it is advantageous to prepare a diagnostic kit comprising a human serine protease-encoding polynucleotide, or a fragment thereof, to use it in diagnosis of a disease or susceptibility to a disease.

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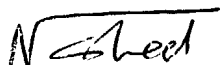
Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
March 22, 2004


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER